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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Robert Thomas Hudak Art Unit : 1641
Serial No. : 09/915,494 Examiner : Gary W. Counts
Filed : July 25, 2001
Title : SPECIMEN COLLECTION CONTAINER



MAIL STOP APPEAL BRIEF – PATENTS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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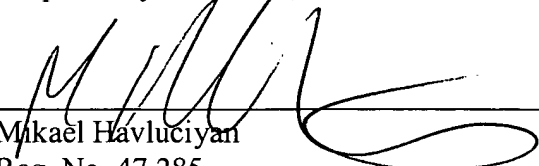
Total Claims	29	-	60	=	0	\$0
Independent	2	-	3	=	0	\$0
First Presentation of Multiple Dependent Claims						\$0

Applicant hereby petitions under 37 C.F.R. §1.136 for a 0 month extension of time.

Appeal Brief Due	\$250
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Respectfully submitted,

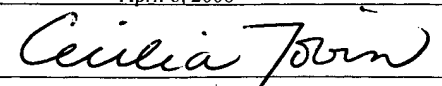

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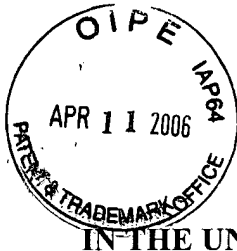
Date: April 6, 2006

PTO Customer No.: 20985
Fish & Richardson P.C.
12390 El Camino Real
San Diego, California 92130
Telephone: (858) 678-5613
Facsimile: (202) 626-7796
Email: havluciyan@fr.com
10618118.doc

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Attorney's Docket No.: 17072-002001 / 0271

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APPEAL BRIEF

Dear Sir:

This is in response to the Notice of Appeal filed February 2, 2006 and the Notice of Panel Decision from Pre-Appeal Brief Review mailed March 6, 2006.

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Real Party in Interest

The real party in interest is the assignee of the present case – Oakville Hong Kong Company, Ltd.

Related Appeals and Interferences

There are presently no related appeals or interferences for this case. However, it is possible that co-pending application Serial No. 10/211,199, filed August 2, 2002 will be placed on appeal at a later date.

Status of Claims

Claims 74-102 are pending in the present case and are on appeal.

Status of Amendments

No amendments were filed subsequent to final rejection.

Summary of Claimed Subject Matter

Claim 74 of the present application claims a specimen collection device. In one embodiment (illustrated in Figure 1 *et seq.*) the device is a urine collection cup having a chamber for collecting a specimen, and a reservoir that receives an aliquot of the specimen from the chamber (specification, page 1, line 22 – p. 3, line 7). The reservoir contains a test device with reagents or chemicals for analyzing the specimen sample (specification, p. 6, lines 21-28). A valve is present between the chamber and the reservoir. The valve contains a valve compartment for holding an aliquot of specimen fluid, and for transferring specimen sample from the chamber to the reservoir without direct contact between the chamber and the reservoir. When the valve is in a first position the valve compartment is in fluid communication with the chamber but is not in fluid communication with the reservoir (which contains the test device). When the valve is in a

second position the valve compartment is not in fluid communication with either the chamber nor the reservoir. When the valve is in a third position the valve compartment is not in fluid communication with the chamber but is in fluid communication with the reservoir (specification, p. 17, lines 19- p. 18, line 5). Thus, the specimen collection device is structured to assure no intermingling of specimen after specimen has contacted the test device in the reservoir. The valve is structured so that it is inoperable after a first activation (specification, p. 20, lines 10-11). This assures that no intermingling of sample aliquots can occur since the valve cannot be returned to its initial position after being activated, nor can it allow specimen sample to flow from the reservoir to the chamber.

Claim 96 of the present application claims a method of detecting an analyte of interest in a specimen sample. The method involves collecting a specimen in a device of the invention, causing an aliquot of specimen to enter the valve compartment, actuating the valve, causing the aliquot of specimen to flow out of the compartment and into the reservoir to contact the test device, and detecting the analyte of interest (specification, p. 36, lines 18-22; p. 37, line 17 – p. 40, line 13).

The specimen collection device of the invention provides important benefits to the user. The device allows a user to test a specimen sample while being assured that no contamination of sample has occurred from chemicals or reagents used on the test device (contained in the reservoir). Thus the invention solves an issue of major concern in the industry of specimen testing. The invention also allows the user to retain an uncontaminated sample for confirmatory testing at an independent facility.

Grounds of Rejection to be Reviewed on Appeal

Whether claims 74-75, 79, 85-92, and 94-102 are properly rejected as being anticipated under 35 U.S.C. 102(e) by Cui et al. (US 6,576,193).

Whether claims 76 is properly rejected as unpatentable under 35 U.S.C. 103(a) over Cui et al. in view of Nelson et al. (US 5,115,934).

Whether claims 77-78 are properly rejected under 35 U.S.C. 103(a) as being unpatentable over Cui et al. in view of Alley (US 2002/00446614).

Whether claims 80 and 84 are properly rejected under 35 U.S.C. 103(a) as being unpatentable over Cui in view of Mitsumaki et al. (US 4,680,270) and Pampinella (US 2002/0023482).

Whether claims 81-83 are properly rejected under 35 U.S.C. 103(a) as being unpatentable over Cui et al. in view of Carter et al. (US 4,909,933).

Whether claim 93 is properly rejected under 35 U.S.C. 103(a) as being unpatentable over Cui et al. in view of Ehrenkranz (US 4,769,215).

Argument

Rejection Under the Judicially Created Doctrine of Obviousness-type Double Patenting

The Examiner provisionally rejected claims 74-102 under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 1-62 of copending U.S. Application No. 10/211,199.

The Applicant has agreed to submit a terminal disclaimer in the present case if the claims in co-pending U.S. Application No. 10/211,199 are allowed before the claims in the present case, and if the claims in both cases are otherwise allowable in their present form (Amendment filed Nov. 30, 2005, p. 9).

Rejection under 35 U.S.C. 102(b) over Cui et al. (US 6,576,193)

The Examiner rejected claims 74-75, 79, 85-92, and 94-102 under 35 U.S.C. §102(b) as allegedly being anticipated by Cui et al.) (Office Action mailed 1/12/06, p. 2).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631; 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP 2131.

The present claims recite that the device comprises a valve that is "inoperable after a first actuation." Cui discloses no such valve, and therefore cannot anticipate the claims.

The Examiner maintains that the recitation of "the valve being inoperable after a first actuation" can be simply ignored, alleging that it is an "intended use" of the valve, and that a recitation of an intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art (Office Action dated 8/31/05, p. 3, line 14).

However, this limitation is not a mere recitation of intended use nor a non-limiting statement in the preamble of the claim, but represents a specific characteristic of the claimed invention and a genuine required limitation of the claim that must be evaluated with every other limitation – the claim requires that the valve be inoperable after a first actuation. Case law clearly establishes that each element contained in a patent claim is deemed material to defining the scope of the invention. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17; 41 USPQ2d 1865 (1997), on remand, 114 F.3d 1161; 43 USPQ2d 1152 (Fed. Cir. 1997) (Order Per Curiam). Even functional language in a claim cannot be simply disregarded. *Pac-Tec, Inc. v. Amerace Corp.* 903 F.2d 796; 14 USPQ2d 1871 (Fed. Cir. 1990), *cert denied sub nom. Perry v. Amerace Corp.*, 502 U.S. 808 (1991) ("in determining anticipation, functional language, preambles, and language in "whereby," "thereby," and "adapted to" clauses cannot be disregarded."). Thus, no legal basis exists for disregarding the recited claim element, nor has the Examiner cited any such basis. Indeed, the Examiner specifically admits that he cites no case law to support the rejection (Office Action mailed 1/12/06, p. 8, lines 16-17). Nor has the Examiner cited any other legal basis for disregarding the claim element. Furthermore, this limitation must be evaluated in view of the specification, which contains relevant disclosure at p. 21, line 10 et seq.

Since Cui does not disclose every limitation of the claim, it cannot anticipate the claim. Relief from the rejection is respectfully requested.

Legal Background for Rejections Under 35 U.S.C. §103

In order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) and MPEP 2142.

Claim 76 stands rejected over Cui et al. in view of Nelson et al. (US 5,115,934)

As discussed above with reference to the 102 rejection, Cui fails to disclose a valve that is inoperable after a first actuation. Nelson also fails to disclose or suggest this limitation of the claim. Therefore, this asserted combination of references does not disclose all of the claim limitations of claim 76, and therefore claim 76 is not unpatentable under 35 U.S.C. 103(a) over this combination of references.

Claims 77-78 stand rejected over Cui et al. in view of Alley (US 2002/00446614)

As discussed above, Cui fails to disclose a valve that is inoperable after a first actuation. Alley also fails to disclose or suggest this limitation of the claims. Therefore, this asserted combination of references does not disclose all of the claim limitations of claims 77-78, and therefore claims 77-78 are not unpatentable under 35 U.S.C. 103(a) over this combination of references.

Claims 80 and 84 stand rejected over Mitsumaki et al. (US 4,680,270) and Pampinella (US 2002/0023482)

As discussed above, Cui fails to disclose a valve that is inoperable after a first actuation. Mitsumaki and Pampinella also fail to disclose or suggest this limitation of the claims. Mitsumaki discloses a rotary valve operable for many activations (Col. 2, lines 37-49). Pampinella discloses a slide valve operable for many activations, as it must be to fulfill its purpose as a leak testing device for plumbing of buildings (paragraphs 0034 and 0044).

Therefore, this asserted combination of references does not disclose all of the claim limitations of claims 80 and 84, and therefore claims 80 and 84 are not unpatentable under 35 U.S.C. 103(a) over this combination of references.

Claims 81-83 stand rejected over Cui et al. in view of Carter et al. (US 4,909,933)

As discussed above, Cui fails to disclose a valve that is inoperable after a first actuation. Carter also fails to disclose or suggest this limitation of the claims. Carter discloses only rotating or cylindrical valves that can be activated multiple times (Col. 2, lines 24-34; Col. 3, lines 14-122; Col. 3, lines 57-63). Therefore, this asserted combination of references does not disclose all of the claim limitations of claims 81-83, and therefore claims 81-83 are not unpatentable under 35 U.S.C. 103(a) over this combination of references.

Claim 93 stands rejected over Cui et al. in view of Ehrenkranz (US 4,769,215)

As discussed above Cui fails to disclose a valve that is inoperable after a first actuation. Alley also fails to disclose or suggest this limitation of the claims. Therefore, this asserted combination of references does not disclose all of the claim limitations of claim 93, and therefore claim 93 is not unpatentable under 35 U.S.C. 103(a) over this combination of references.

Therefore, for these reasons and those already described above, the presently claimed invention is not obvious over any combination of the cited references.

Claims Appendix

74. A specimen collection device, comprising:
- (a) a chamber for collecting a specimen;
 - (b) a reservoir for receiving an aliquot of specimen from the chamber and for receiving a test device;
 - (c) a valve functionally interposed between the chamber and the reservoir and having a compartment for holding an aliquot of specimen and transporting the aliquot from the chamber to the reservoir, the valve having first, second and third positions,
- wherein
- when the valve is in the first position, the valve compartment is in fluid communication with the chamber and is not in fluid communication with the reservoir;
- when the valve is in the second position, the valve compartment is not in fluid communication with the chamber nor the reservoir;
- when the valve is in the third position, the valve compartment is in fluid communication with the reservoir and is not in fluid communication with the chamber; and
- the valve being inoperable after a first actuation.
75. The specimen collection device of claim 74, wherein the device comprises a lid for sealing the chamber.
76. The specimen collection device of claim 75, wherein the lid is a tamper resistant lid or tamper evident lid.
77. The specimen collection device of claim 75, wherein the lid comprises at least one O-ring.
78. The specimen collection device of claim 75, wherein when the chamber is sealed with the lid, the lid does not leak specimen between the chamber and the exterior at an internal pressure of up to 100 pounds per square inch.

79. The specimen collection device of claim 74, wherein the reservoir firmly engages the test device.

80. The specimen collection device of claim 74, wherein the valve is a piston valve.

81. The specimen collection device of claim 74, wherein said valve has at least one valve O-ring.

82. The specimen collection device of claim 74, wherein said valve has two or more O-rings.

83. The specimen collection device of claim 74, wherein the valve does not leak specimen between the chamber and the reservoir at an external pressure of up to 100 pounds per square inch.

84. The specimen collection device of claim 74, wherein the valve includes a handle for actuating the valve, wherein the handle functionally disengages from the valve after the valve is actuated and wherein the valve cannot be actuated with the handle disengaged therefrom.

85. The specimen collection device of claim 74, further comprising at least one test device present in the reservoir.

86. The specimen collection device of claim 85, wherein the test device comprises at least one test strip.

87. The specimen collection device of claim 86, wherein the test strip comprises reagents for performing at least one specific binding reaction.

88. The specimen collection device of claim 86, wherein the test strip comprises reagents for an immunoassay.

89. The specimen collection device of claim 86, wherein the test strip comprises reagents for an enzymatic reaction.

90. The specimen collection device of claim 86, wherein the test strip comprises reagents for a chemical reaction.

91. The specimen collection device of claim 91, wherein the analyte of interest is selected from the group consisting of a drug, a drug of abuse, a hormone, a protein, a nucleic acid molecule, an etiological agent and a specific binding member.

92. The specimen collection device of claim 74, wherein the reservoir comprises a port for receiving the test device.

93. The specimen collection device of claim 74, wherein the test device comprises an adulteration determination device.

94. The specimen collection device of claim 74, wherein the specimen is a liquid specimen.

95. The specimen collection device of claim 74, wherein the specimen is a biological specimen.

96. A method of detecting an analyte of interest in a specimen, comprising:

- a) collecting a specimen in a test device comprising;
 - i) a chamber for collecting and holding the specimen;
 - ii) a reservoir for receiving an aliquot of specimen and having a test device; and
 - iii) a valve functionally interposed between the chamber and the reservoir and having a compartment for holding the aliquot, and having a first position wherein the compartment is in fluid communication with the chamber, and a second position wherein the compartment is separated from fluid communication with both the chamber and the reservoir, wherein the valve is inoperable after a first actuation;
- b) causing an aliquot of specimen to enter the compartment of the valve;
- c) actuating the valve;
- d) causing the aliquot of specimen to flow out of the compartment and into the reservoir to contact the test device; and
- e) detecting the analyte of interest.

97. The method of claim 96 wherein actuation of the valve comprises causing the valve to move from the first to the second position, and then to a third position where the compartment is in liquid communication with the reservoir and is not in liquid communication with the chamber.

98. The specimen collection device of claim 96 wherein the test device comprises a test strip having reagents for detecting the presence of at least one analyte of interest.

99. The method of claim 96 wherein the test device comprises a test strip comprising reagents for conducting an immunoassay.

100. The method of claim 100 wherein after the specimen aliquot contacts the reagents for conducting an immunoassay, visible indicators become present on the test strip indicating the presence or absence of the analyte of interest.

101. The method of claim 96 wherein the specimen is a biological specimen.

102. The method of claim 96 wherein the analyte of interest is selected from the group consisting of: a drug of abuse, a hormone, a protein, a nucleic acid molecule, an etiological agent and a specific binding member.

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Evidence Appendix

None

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Related Proceedings Appendix

None

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Closing

The U.S. Patent & Trademark Office is authorized to debit deposit account #06-1050 for any charges related to extension fees or other fees that may be due with this filing and that are not otherwise included herein.

Applicants respectfully submit that the pending claims are in condition for allowance and respectfully request that all rejections be reversed.

Respectfully submitted,



Mikael Havluciyan
Reg. No. 47,285

Date: April 6, 2006

USPTO Customer No.: 20985

Fish & Richardson, P.C.
12390 El Camino Real
San Diego, California 92130
Tel: (858) 678-5613
Fax: (202) 626-7796
Email: havluciyan@fr.com

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